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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,276	07/17/2003	Stuart L. Schreiber	2001180-0075	3033

7590 07/28/2005

PATENT DEPARTMENT
CHOATE, HALL & STEWART
Exchange Place
53 State Street
Boston, MA 02109

EXAMINER

WARD, PAUL V

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/621,276

Applicant(s)

SCHREIBER ET AL.

Examiner

PAUL V. WARD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

- I. The compounds and compositions according to claims 1-54 of formula I, wherein Y is H, aliphatic, alicyclic. These are classifiable in class 549, subclass various.
- II. The compounds and compositions according to claims 1-54 of formula I, wherein Y is heterocyclic, heteroaliphatic, heteroaromatic. These are classifiable in classes 544, 546, 548 subclass various.
- III. The compounds and compositions according to claims 1-54 of formula I, wherein Y is aromatic. These are classifiable in class 549, subclass 357+.
- IV. The method according to claims 55-57, wherein Y is H, aliphatic, alicyclic. This claim is drawn to a method that is classifiable in class 424.
- V. The method according to claims 55-57, wherein Y is heterocyclic, heteroaliphatic, heteroaromatic. This claim is drawn to a method that is classifiable in class 424.
- VI. The method according to claims 55-57, wherein Y is aromatic. This claim is drawn to a method that is classifiable in class 424.
- VII. The method of treating according to claim 58, wherein Y is H, aliphatic, alicyclic. This claim is drawn to a method of treatment that is classifiable in class 514.
- VIII. The method of treating according to claim 58, wherein Y is heterocyclic, heteroaliphatic, heteroaromatic. This claim is drawn to a method of treatment that is classifiable in class 514.

- IX. The method of treating according to claim 58, wherein Y is aromatic. This claim is drawn to a method of treatment that is classifiable in class 514.
- X. The method of synthesizing according to claim 60, wherein Y is H, aliphatic, alicyclic. This method is classifiable in class 549.
- XI. The method of synthesizing according to claim 60, wherein Y is heterocyclic, heteroaliphatic, heteroaromatic. This method is classifiable in classes 544, 546, 548.
- XII. The method of synthesizing according to claim 60, wherein Y is aromatic. This method is classifiable in class 549.

Inventions in Group I-III and Group IV-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be practiced with another materially different product such as anti-tumor or anti-proliferative agents.

Inventions of Group I-III and groups X-XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process as claimed can be used to make other and materially different dioxanes.

The inventions of Groups I-XII are separate and patentably distinct because there is no patentable co-action among them and a reference anticipating one member will not render another obvious.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, a search of the twelve groups designated above would impose an undue burden upon the examiner, and restriction for examination purposes as indicated is proper.

A telephone call was made to Nadege Lagneau on July 21, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is requested to elect a specifically disclosed species of the invention to be examined for search purposes.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

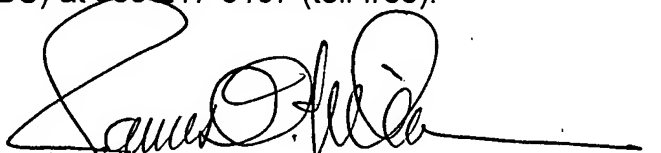
Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James O. Wilson
Supervisory Patent Examiner,
Technology Center 1600